SECTION 2: EXECUTIVE SUMMARY

Intended Use:

chromID™ MRSA agar is a selective and differential chromogenic medium for the qualitative detection of nasal colonization by methicillin-resistant *S. aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test is performed on anterior nares swab specimens from patients and healthcare workers to screen for MRSA colonization. chromID™ MRSA agar is not intended to diagnose MRSA infection nor to guide or monitor treatment for infections.

Device Description:

chromID™ MRSA agar is a selective and differential chromogenic medium for the qualitative detection of MRSA from anterior nares swab specimens.
chromID™ MRSA agar consists of a rich nutritive base combining different peptones. It also contains a chromogenic substrate of α-glucosidase and a combination of several antibiotics, which favor the growth of MRSA including hetero-resistant strains. The antibiotics include: cefoxitin (4 mg/l), aztreonam (64 mg/l), and amphotericin B (3 mg/l). The selective mixture of antibiotics inhibits most bacteria not belonging to the genus *Staphylococcus*, as well as yeasts. The MRSA strains are identified by the presence of green colonies that result from the chromogen incorporated in the medium. The chromogen targets the α-glucosidase activity of *S. aureus*. The α-glucosidase produced by *S. aureus* cleaves the chromogenic substrate, which gives a green color to the *S. aureus* colonies growing on the medium. This chromogen is identified as "Green α-glucoside" (5-Bromo-4-chloro-3-indoxyl-N-methyl-α-D-glucoside) (patent registered).

Device Comparison Table:

The similarities and differences of ChromID™ MRSA agar when compared to the predicate device are described in the following table.

Item	Device chromID™ MRSA Agar	Predicate BBL™ CHROMagar™ MRSA
Similarities		
Intended Use	chromID™ MRSA agar is a selective and differential chromogenic medium for the qualitative detection of nasal colonization by methicillin-resistant *S. aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test is performed on anterior nares swab specimens from patients and healthcare workers to screen for MRSA colonization. chromID™ MRSA agar is not intended to diagnose MRSA infection nor to guide or monitor treatment for infections.	BBL™ CHROMagar™ MRSA is a selective and differential medium for the qualitative direct detection of nasal colonization by methicillin resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test is performed on anterior nares swab specimens from patients and healthcare workers to screen for MRSA colonization. BBL™ CHROMagar™ MRSA is not intended to diagnose MRSA infection nor to guide or monitor treatment for infections.
Test method	Manual	Manual
Inoculum	Direct Specimen	Direct Specimen
Specimen	Anterior nares specimens	Anterior nares specimens

Item	Device chromID™ MRSA Agar	Predicate BBL™ CHROMagar™ MRSA
Differences		
Detection method	chromID™ MRSA contains a chromogenic substrate and a combination of several antibiotics including cefoxitin. The chromogenic substrate provides for the direct detection of MRSA by revealing α-glucosidase activity which produces green colonies (patent registered).	*BBL™ CHROMagar™* MRSA contains specific chromogenic substrates and cefoxitin. MRSA strains growing in the presence of these substrates will produce mauve-colored colonies resulting from hydrolysis of the chromogenic substrate.
Incubation Conditions	24h at 35-37°C in aerobic conditions	24-48 h in 33-37°C in aerobic conditions

Discussion:

Both devices have similar Intended Use statements. The technological characteristics are similar but not identical. Both devices, chromID™ MRSA agar and BBL™ CHROMagar™ MRSA, are chromogenic media incorporated with cefoxitin for the direct detection of methicillin resistant *Staphylococcus aureus* from anterior nares specimens. Both devices incorporate selective agents in the agar to most bacteria not belonging to the genus *Staphylococcus*, as well as yeasts. chromID™ MRSA agar contains chromogenic substrates that reveal α-glucosidase activity of MRSA strains and produce green colonies. BBL™ CHROMagar™ MRSA contains specific chromogenic substrates. MRSA strains growing in the presence of these substrates will produce mauve-colored colonies resulting from hydrolysis of the chromogenic substrate

The safety and effectiveness of the chromID™ MRSA agar is not impacted by the technology differences. The chromID™ MRSA agar utilizes nutrient agar medium that contains selective and differential agents and is very similar to the BBL™ CHROMagar™ MRSA agar. The significant technological difference between the two media is the type of chromogenic substrate incorporated in the media to indicate the presence of MRSA colonies.

Clinical studies were performed and demonstrate acceptable performance of chromID™ MRSA. The overall agreement for detection of MRSA and non-MRSA by chromID™ MRSA compared to conventional methods including the identification and susceptibility testing was 98.6% (1242/1259) at 24 h. Performance comparisons to confirmed MRSA and non-MRSA strains can be found in the following table:

Clinical Performance Compared to Conventional Methods after 24 h Incubation:

Methods	MRSA	Non-MRSA
cMRSA	94.7% (304/321) 95% CI = 91.7 – 96.9%	100.0% (938/938) 95% CI = 99.6 – 100%
TSAB	91.6% (294/321) 95% CI = 88.0 – 94.4%	100.0% (938/938) 95% CI = 99.6 – 100%
cMRSA vs. Latex Agglutination	96.3% (309/321) 95% CI = 93.6 – 98.1%	98.4% (923/938) 95% CI = 97.4 – 99.1%
cMRSA vs. Cefoxitin Screen	96.3% (309/321) 95% CI = 93.6 – 98.1%	98.4% (923/938) 95% CI = 97.4 – 99.1%
cMRSA vs. *mecA* PCR	100.0% (321/321) 95% CI = 98.9 – 100%	97.9% (918/938) 95% CI = 96.7 – 98.7%

CI = Confidence Interval

Performance is based on the number of true positives detected from either medium during the trial (true positives = number of samples positive by TSAB + number of samples that are false negative by TSAB and positive by chromID™ MRSA).

Conclusion:

The analytical and clinical performance data presented in this submission support a substantial equivalence decision. Based on the Substantial Equivalence Decision Tree, the chromID™ MRSA agar is substantially equivalent to the BBL™ CHROMagar™ MRSA agar.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Hazelwood, Missouri 63042

JUL 17 2009

Re: k091024
Trade/Device Name: chromID™ MRSA Agar
Regulation Number: 21 CFR 866.1700
Regulation Name: Antimicrobial susceptibility test
Regulatory Class: II
Product Code: JSO
Dated: July 8, 2009
Received: July 9, 2009

Dear Ms. Weaver,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office or In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091024

Device Name: chromID™ MRSA Agar

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091024